

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE**

HEATHER WOODBURY,

Plaintiff,

v.

**ETHICON, INC. and JOHNSON &
JOHNSON,**

Defendants.

**COMPLAINT AND
JURY DEMAND**

No. _____

CIVIL ACTION COMPLAINT

Plaintiff, HEATHER WOODBURY (“Plaintiff”), by and through her counsel, brings this Complaint to set forth against Defendants’ ETHICON, INC., and JOHNSON & JOHNSON (collectively, “Defendants’”, as the context may require) for injuries suffered as a result of the implantation of defective pelvic mesh products designed, manufactured and marketed by Defendants’. In support, Plaintiff states and avers as follows:

PARTIES

1. Plaintiff Heather Woodbury, is, and was, at all relevant times, a citizen and resident of the state of Maine, county of Somerset.

2. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

3. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson and is incorporated in the state of New Jersey with its principal place of business in Somerville, New Jersey.

4. Defendants ETHICON, INC. and JOHNSON & JOHNSON share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities

relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as “Defendants”.

5. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

JURISDICTION AND VENUE

6. Damages sought in this matter are in excess of \$75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

7. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

8. Venue on remand is proper in the District Court of Maine pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district.

9. Defendants conducted substantial business in the State of Maine and in this District, distribute Pelvic Mesh Products in this District, receive substantial compensation and profits from sales of Pelvic Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

10. Defendants conducted business in the State of Maine through sales representatives conducting business in the State of Maine and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, Pelvic Mesh Products; thus, there exists a sufficient nexus between Defendant forum contacts and the Plaintiff’s claims to justify assertion of jurisdiction in Maine.

11. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Maine such that requiring an appearance does not offend traditional notions of fair play and substantial justice.

DEFENDANTS' PELVIC MESH PRODUCTS

12. In or about October, 2002, the Defendants began to market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

13. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

14. In or about September, 2005, the Defendants began to market and sell a product known as Prolift, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift include by reference all variations.

15. In or about May, 2008, the Defendants began to market and sell a product known as Prolift+M, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift+M was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift+M include by reference all variations.

16. The Defendants market and sell a product known as TVT, for the treatment of stress urinary incontinence in females. The TVT has been and is offered in multiple variations including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT include by reference all variations.

17. The products known as Prolene Mesh, Gynemesh, Prolift, Prolift+M, and TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar purposes, inclusive of the instruments and procedures for implantation, are collectively referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.

18. Defendants' Pelvic Mesh Products were designed, patented, manufactured, labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.

FACTUAL BACKGROUND

19. On November 14, 2013, Plaintiff was implanted with an Ethicon/Johnson & Johnson TVT-O ("Pelvic Mesh Products", "Pelvic Mesh Product", and/or "Product") during surgery performed at Maine General Medical Center in Augusta, Maine.

20. The Pelvic Mesh Product was implanted in Plaintiff to treat her urinary incontinence, the use for which the Pelvic Mesh Product were designed, marketed and sold.

21. On March 23, 2017, Plaintiff underwent revision surgery of the Ethicon/Johnson & Johnson TVT-O product at Maine General Medical Center in Augusta, Maine. The revision surgery was necessary because the TVT-O product implanted in Plaintiff had eroded and the mesh had become exposed causing Plaintiff to suffer from pain with daily activities and dyspareunia.

22. As a result of having the Product implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury and permanent and substantial physical deformity and has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

23. Defendants' Pelvic Mesh Product has been and continues to be marketed to the medical community and to patients as a safe, effective, reliable, medical device; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

24. The Defendants have marketed and sold the Defendants' Pelvic Mesh Product to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable consideration and benefits to health care providers. Also utilized are documents, brochures, websites, and telephone information lines, offering exaggerated and misleading expectations as to the safety and utility of the Defendants' Pelvic Mesh Product.

25. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Product has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff.

26. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Product to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Product, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

27. Defendants have known and continue to know that their disclosures to the FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Product was and is causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Defendants' Pelvic Mesh Product was and is safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Product into the Plaintiff.

28. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' Pelvic Mesh Product.

29. Defendants failed to design and establish a safe, effective procedure for removal of the Defendants' Pelvic Mesh Product; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh Product.

30. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation and treatment of stress urinary incontinence, pelvic organ prolapse, and similar other conditions have existed at all times relevant as compared to the Defendants' Pelvic Mesh Product.

31. The Defendants' Pelvic Mesh Product was at all times utilized and implanted in a manner foreseeable to the Defendants.

32. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' Pelvic Mesh Product, and thus increase the sales of the Product, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

33. The Pelvic Mesh Product implanted into the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

34. The injuries, conditions, and complications suffered due to Defendants' Pelvic Mesh Product include but are not limited to mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiff's intimate partners.

35. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Product, the Defendants have, and continue to manufacture, market, and sell the Product, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Product, both prior to and after the marketing and sale of the Product.

COUNT I
STRICT LIABILITY – FAILURE TO WARN
14 M.R.S. § 221

36. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

37. At all relevant times Defendants were "sellers" under 14 M.R.S. § 221, of Pelvic Mesh Products, including the Ethicon/Johnson & Johnson TVT-O device implanted in Plaintiff.

38. The Defendants failed to properly and adequately warn and instruct the Plaintiff

and her health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Product.

39. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Product, given the Plaintiff's conditions and need for information

40. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Product, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Product.

41. In addition, the Products were defective due to the lack of necessary and appropriate warnings regarding, but not limited to, the following:

- a) the Products' propensities to contract, retract, and/or shrink inside the body;
- b) the Products' propensities for degradation, fragmentation, disintegration and/or creep;
- c) That the Defendants' device was defective, and caused dangerous and adverse side effects, including but not limited to higher incidence of erosions, extrusions, adverse tissue response and rejection, contraction, migration, trauma, groin pain, vaginal pain, failure, and revision surgeries at a much more significant rate than other products, treatments and procedures available to treat pelvic organ prolapse;
- d) That patients needed to be monitored more regularly than usual while using the Defendants' device and that in the event the product needed to be attempted to revise or be removed that the procedures to remove segments of the product had a very high failure rate and/or needed to be performed repeatedly;
- e) the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;
- f) the rate and manner of mesh erosion or extrusion;
- g) the risk of chronic inflammation resulting from the Products;
- h) the risk of chronic infections resulting from the Products;
- i) the risk of permanent vaginal or pelvic scarring as a result of the Products;

- j) the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;
- k) the need for corrective or revision surgery to adjust or remove the Products;
- l) the severity of complications that could arise as a result of implantation of the Products
- m) the hazards associated with the Products;
- n) the Products' defects described herein
- o) treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;
- p) treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;
- q) treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;
- r) use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
- s) removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
- t) complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

42. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Product, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

43. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

44. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiffs demand judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II
STRICT LIABILITY – DESIGN DEFECT
14 M.R.S. § 221

45. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

46. At the time of Plaintiff's injuries, the Defendants' Pelvic Mesh Product was defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warnings labels and instructions were deficient.

47. The TVT-O Product was placed into the stream of commerce by the Defendants, as "sellers" under 14 M.R.S. § 221, with the expectation that it would reach consumers in Maine without substantial change in condition and, as of November 14, 2013, there had been no substantial change in the condition of the TVT-O Product.

48. The TVT-O implanted in Heather Woodbury was in the same or substantially similar condition as when it left the Defendants' possession, and in the condition directed by and expected by the Defendants.

49. The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective with respect to its design, as described herein, in that such design and manufacture posed an unreasonable risk of harm to patients in whom the Products were implanted.

50. The Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

51. The Products create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Products.

52. The Defendants have intentionally and recklessly manufactured, the Products with wanton and willful disregard for the rights and health of the Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

53. The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, the Products' design defects include, but are not limited to:

- a) the use of polypropylene material and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;
- b) the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;
- c) biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;
- d) the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;
- e) the propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;
- f) the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);
- g) the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;
- h) the propensity of the Products for particle loss or "shedding", which causes a

chronic inflammatory response and fibrotic reaction, and results in continuing injury over time; the lack of porosity of the Products, which leads to fibrotic bridging and results in continuing injury over time; and

- i) the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

54. Plaintiff adopts the Plaintiff adopts the *Restatement of Torts (Second)* and/or the *Restatement of Torts (Third)*, bringing strict product liability claims under the common law, *Section 402A of the Restatement of Torts (Second)*, and/or *Restatement of Torts (Third)*) against Defendants and 14 M.R.S. § 221.

55. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

56. Specifically, the TVT-O implanted in Heather Woodbury eroded and became exposed causing Plaintiff to suffer from severe complications, including but not limited to: severe pain with daily activities, dyspareunia and economic damages.

57. The Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because the Defendants negligently misrepresented the Products' high risk of unreasonable, dangerous, adverse side effects.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
NEGLIGENCE

58. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

59. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Pelvic Mesh Product, and recruitment and training of physicians to implant the Pelvic Mesh Product.

60. Defendants breached their duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the Pelvic Mesh Product.

61. At all times material, Defendants failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its Pelvic Mesh Product was not properly manufactured, compounded, assembled, inspected, packaged, distributed, tested, analyzed, examined, or prepared, such that the medical device was defective, unreasonably dangerous, and likely to injure its users, including Plaintiff herein.

62. Also, Defendants failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its Pelvic Mesh Products were sold without sufficient warnings or instruction (both before as well as after their sale), such that the TVT-O mesh device was likely to injure its users, including Plaintiff herein.

63. As a result of said failures, the TVT-O brand mesh device implanted in Plaintiff was unreasonably dangerous and defective in design and unaccompanied by adequate warnings concerning its hazardous properties.

64. Further, Defendants failed to exercise reasonable care under the circumstances, as it knew, or in the exercise of reasonable care, should have known, that its Pelvic Mesh Products and the information (including warnings, instructions, detailing, advertising, promotion, and

representations) about the characteristics and properties of the device; the potential risks associated with its use in patients; safety and efficacy data; the attributes of the device relative to other competing medical devices; and the management of patients after implantation of this device were inaccurate or incomplete, such that the medical device was likely to injure its users, including Plaintiff herein.

65. Defendants also failed to conduct sufficient testing, quality assurance measures and/or inspection of its Pelvic Mesh Product, both prior to and after clearance of the product for sale, which, if properly performed, would have revealed or led, long ago, to the detection of defects in the Pelvic Mesh Product and inadequacy in the warnings, promotional materials and instructions which accompanied the device, such that the injuries suffered by Plaintiff herein could have been prevented.

66. These negligent acts by Defendants resulted in the sale of Pelvic Mesh Products that were unreasonably dangerous, unsafe, and not reasonably fit for the uses and purposes for which the medical device would ordinarily be put or some other reasonably foreseeable purpose and the unreasonably dangerous condition existed when such device, including the particular device implanted in Plaintiff, left Defendants' custody and control.

67. Defendants knew or should have known that the Pelvic Mesh Product subjected Plaintiff to unreasonably dangerous risks of which the Plaintiff and her treating physicians would not be aware. Nevertheless, Defendants advertised, marketed, sold and distributed the Pelvic Mesh Product device for years to thousands of women, at a time when Defendants knew that there were safer methods and products available for the treatment of pelvic organ prolapse.

68. Had Plaintiff, her treating physician, or both known of the unreasonably dangerous risks associated with the TVT-O product at the time of her implant surgery, such knowledge would have affected the treating physician's use of the device and Plaintiff would not have consented to

the implantation of the device.

69. As a proximate result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff has been injured, often catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV
NEGLIGENT MISREPRESENTATION

70. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

71. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Pelvic Mesh Product had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

72. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Product while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Product's high risk of unreasonable, dangerous, adverse side effects.

73. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Product has no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

74. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Product had been insufficiently tested, or had not been tested at all, and that it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

75. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V
BREACH OF EXPRESS WARRANTY

76. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

77. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Product.

78. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Product be used in the manner that Plaintiff in fact used it and Defendants expressly warranted that the product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other pelvic mesh products, and that it was adequately

tested and fit for its intended use.

79. At all relevant times, Defendants were aware that consumers, including Plaintiff, would use the Pelvic Mesh Product; which is to say that Plaintiff was a foreseeable user of the Defendants' Pelvic Mesh Product.

80. Plaintiff and/or her implanting physicians were at all relevant times in privity with Defendants.

81. The Defendants' Pelvic Mesh Product was expected to reach and did in fact reach consumers, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

82. Defendants breached various express warranties with respect to the Pelvic Mesh Product including the following particulars:

- a) Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Product was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Product;
- b) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Product was as safe, and/or safer than other alternative procedures and devices and fraudulently concealed information, which demonstrated that the Product was not safer than alternatives available on the market; and
- c) Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' Pelvic Mesh Product was more efficacious than other alternative

medications and fraudulently concealed information, regarding the true efficacy of the product.

83. In reliance upon Defendants' express warranty, Plaintiff was implanted with the Defendants' Pelvic Mesh Product as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

84. At the time of making such express warranties, Defendants knew or should have known that the Defendants' Pelvic Mesh Product does not conform to these express representations because the Defendants' Pelvic Mesh Product was not safe and had numerous serious side effects, many of which Defendants did not accurately warn about, thus making the Defendants' Pelvic Mesh Product unreasonably unsafe for its intended purpose.

85. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and the Public relied upon the representations and warranties of Defendants in connection with the use recommendation, description, and/or dispensing of the Defendants' Pelvic Mesh Product.

86. Defendants breached their express warranties to Plaintiff in that the Defendants' Pelvic Mesh Product was not of merchantable quality, safe and fit for its intended uses, nor was it adequately tested.

87. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI
BREACH OF IMPLIED WARRANTY OF
MERCHANTABILITY
11 M.R.S. § 2-314

88. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

89. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Product.

90. Defendants are "merchants" within the definition of 11 M.R.S. § 2-314.

91. The TVT-O device implanted in Plaintiff, which was designed, manufactured and sold by Defendants, did not work properly to resolve her stress urinary incontinence and was unexpectedly harmful in causing erosion and requiring a revision surgery.

92. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Product be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

93. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' Pelvic Mesh Product in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the Defendants' Pelvic Mesh Product.

94. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

95. The Defendants' Pelvic Mesh Product was expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

96. Defendants breached various implied warranties with respect to the Defendants' Pelvic Mesh Product, including the following particulars:

- a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Product was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Pelvic Mesh Product;
- b) Defendants represented that the Defendants' Pelvic Mesh Product was safe, and/or safer than other alternative devices or procedures and fraudulently concealed information, which demonstrated that the Defendants' Pelvic Mesh Product was not as safe or safer than alternatives available on the market; and
- c) Defendants represented that the Defendants' Pelvic Mesh Product was more efficacious than alternative pelvic mesh products and procedures and fraudulently concealed information, regarding the true efficacy of the Defendants' Pelvic Mesh Product.

97. In reliance upon Defendants' implied warranty, Plaintiff used the Pelvic Mesh Product as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

98. Defendants breached their implied warranty to Plaintiff in that the Defendants' Pelvic Mesh Product was not of merchantable quality, safe and fit for its intended use, or adequately tested.

99. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive

damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII
VIOLATION OF CONSUMER PROTECTION ACT
5 M.R.S.A. §§ 205-A et seq.
(Maine Unfair Trade Practice Act)

100. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

101. Plaintiff purchased and used the Defendants' Pelvic Mesh Product primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

102. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Product, and would not have incurred related medical costs and injury.

103. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

104. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- a) Representing that goods or services has characteristics, ingredients, uses benefits or quantities that they do not have;
- b) Advertising goods or services with the intent not to sell them as advertised;
and,
- c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

105. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Product. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Product.

106. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Product.

107. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Product, and would not have incurred related medical costs.

108. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of 5 M.R.S.A. §§ 205-A *et seq.* (Maine Unfair Trade Practice Act).

109. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of 5 M.R.S.A. §§ 205-A *et seq.* (Maine Unfair Trade Practice Act).

110. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations.

111. Under applicable state statutes enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales

practices.

112. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh Product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

113. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

114. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' Pelvic Mesh Product and failed to take any action to cure such defective and dangerous conditions.

115. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

116. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

117. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

118. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them,

individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII
GROSS NEGLIGENCE

119. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

120. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with applicable Federal standards: was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

121. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

122. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

123. Plaintiff also alleges that the acts and omissions of named Defendants, whether

taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX
PUNITIVE DAMAGES

124. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

125. At all times relevant hereto, Defendants knew or should have known that the Defendants' Pelvic Mesh Product was inherently more dangerous with respect to the risks of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

126. At all times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Defendants' Pelvic Mesh Product.

127. Defendants' misrepresentation included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Defendants' Pelvic Mesh Product.

128. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Product causes debilitating and potentially lethal side effects

with greater frequency than safer alternative methods products and/or procedures and/or treatment.

129. At all times material hereto, Defendants knew and recklessly disregarded the fact that the Defendants' Pelvic Mesh Product causes debilitating and potentially lethal side effects with greater frequency than safer alternative products and/or methods of treatment and recklessly failed to advise the FDA of same.

130. At all times material hereto, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the risk of injuries caused by the Defendants' Pelvic Mesh Product.

131. Notwithstanding the foregoing, Defendants continue to aggressively market the Defendants' Pelvic Mesh Product to consumers, without disclosing the true risk of side effects when there were safer alternatives.

132. Defendants knew of the Defendants' Pelvic Mesh Product defective and unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Defendants' Pelvic Mesh Product so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by the Defendants' Pelvic Mesh Product.

133. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Defendants' Pelvic Mesh Product in order to ensure continued and increased sales.

134. Defendants' intentionally reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the Defendants' Pelvic Mesh Product against her benefit.

135. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and has incurred medical, health care, incidental,

and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical care and/or hospital care and medical services.

136. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant Common Law principles.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- A. All general, statutory, and compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present;
- B. All special and economic damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, pain and suffering;
- C. Attorneys' fees, expenses, and costs of this action;
- D. Double or triple damages as allowed by law;
- E. Punitive and/or exemplary damages;
- F. Pre-judgment and post-judgment interest in the maximum amount allowed by land; and
- G. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated this 3rd day of August, 2020.

Respectfully Submitted,

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